

**LABEL, IN PART:** "25 cc. Sterile Solution Estrogenic Material in Oil 30,000 [or "10,000," or "50,000"] Int. Units per cc."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statement, "This Estrogenic Material Contains Estrodial, Estrone and other Estrogenic factors of Pregnant Mares Urine," was false and misleading as applied to the article.

**DISPOSITION:** October 9, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1794. Misbranding of Estrol. U. S. v. 78 Cartons of Estrol. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No 16419. Sample No. 16256-H.)**

**LIBEL FILED:** June 13, 1945, Northern District of Illinois.

**ALLEGED SHIPMENT:** On or about March 26, 1945, from New York, N. Y., by the C. F. Kirk Co.

**PRODUCT:** 78 cartons, each containing 1 vial, of *Estrol* at Chicago, Ill. Examination showed that the product was an oil solution containing estrogenic substances consisting essentially of estradiol, with no significant proportion of estrone, which is the principal estrogenic hormone occurring in natural sources such as equine urine.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the statements on the vial label, "Natural Estrogen obtained from Equine Urine," and on the carton label, "Estrogenic Hormones obtained from Equine Urine," were false and misleading since the estrogenic material present in the article did not consist of natural estrogenic substance as derived from equine urine.

**DISPOSITION:** July 2, 1945. The Gamma Pharmaceutical Co., Chicago, Ill., claimant, having admitted the facts of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

**1795. Misbranding of estrogen in peanut oil. U. S. v. 53 Vials of Estrogen in Peanut Oil. Default decree of condemnation and destruction. (F. D. C. No. 16099. Sample No. 16216-H.)**

**LIBEL FILED:** May 23, 1945, Northern District of Illinois.

**ALLEGED SHIPMENT:** On or about March 1, 1945, by the Pro-Medico Laboratories, Inc., from Brooklyn, N. Y.

**PRODUCT:** 53 vials of *estrogen in peanut oil*, at Chicago, Ill. Examination showed that the product was an oil solution of estrogenic material consisting essentially of estradiol, with no significant proportion of estrone, the principal estrogenic hormone in prenatal mares' urine. There were no labels upon the immediate containers, the glass vials, as they were shipped, and there was no agreement between the shipper and the consignee with respect to labeling the vials.

**LABEL, IN PART:** (Cartons) Gynestrin 30 cc size \* \* \* A sterile oil solution of di-hydro derivatives of estrogenic substances and estrogen substance derived from equine urine."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the statement on the carton, "A sterile oil solution of di-hydro derivatives of estrogenic substances and estrogen substance derived from equine urine," was false and misleading since the estrogenic material present did not consist of estrogenic material as extracted from equine urine; Section 502 (b) (1), the product was a drug in package form and the individual vials failed to bear a label stating the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the labels failed to bear an accurate statement of the quantity of the contents of the vials in terms of measure; and, Section 502 (e), the article was a drug fabricated from two or more ingredients, but its label failed to bear the common or usual name of each active ingredient, since the carton label did not bear the name "estradiol," which is the common or usual name of the principal active ingredient of the article, and the vials had no label whatever.

**DISPOSITION:** September 14, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1796. Misbranding of infrared bulbs. U. S. v. 11 Packages of Infrared Bulbs, and 11 circulars. Default decree of condemnation and destruction. (F. D. C. No. 16476. Sample No. 12994-H.)**

**LIBEL FILED:** June 20, 1945, Southern District of Ohio.

**ALLEGED SHIPMENT:** On or about April 12, 1945, by the U. S. Medical Specialty Co., from Minneapolis, Minn.

**PRODUCT:** 11 packages, each containing an *infrared bulb*, and 11 circulars entitled "A New Scientific Development," at Cincinnati, Ohio. The circulars were enclosed in the shipping carton containing the packages of bulbs. Examination showed that the product was a device consisting of a ruby glass electric bulb, partially silvered on the inside and designed to produce heat.

**LABEL, IN PART:** (Packages) "375 Watt 120 Volt Mis-35-N. Ruby Ins. Silvered Medium Base," and "U. S. C. O. Reflector Infra-Red Bulb."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the following statements in the circulars were false and misleading since they represented and suggested that the product would be an adequate treatment for the conditions stated and implied, whereas the only therapeutic function of the article would be the production of heat, and heat does not constitute an adequate treatment for those conditions: "If you are suffering from any of the following ailments, we suggest you consult your doctor about using infra-red rays for relief. Prostatic Troubles Sprains \* \* \* Sinus trouble Neuralgia Rheumatism Lumbago Neuritis Pleurisy Pneumonia Tonsillitis Influenza Arthritis Bronchitis Catarrh Asthma Fractures Womens ailments Deafness Ear Trouble Skin Diseases Torticollis Boils when open Cholecystitis Endocarditis Low red blood count To Raise Lowered Vitality To Improve Nervous System To Relieve Pain To Improve Circulation To Promote Absorption of Exudate To Increase Red Blood Count And many others \* \* \* For superficial conditions, such as infections, acute inflammations \* \* \* deep-seated lesions \* \* \* For general systematic treatment \* \* \* tends to induce active circulation."

Further misbranding, Section 502 (b) (1), the product failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

**DISPOSITION:** August 29, 1945. No claimant having appeared, judgment of condemnation was entered and the product, together with the circulars, was ordered destroyed.

#### DRUGS ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENTS STATEMENTS\*

**1797. Misbranding of estrogenic substance in oil. U. S. v. 5 Bottles of Estrogenic Substance in Oil. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 16444. Sample No. 17634-H.)**

**LABEL FILED:** June 16, 1945, Eastern District of Michigan.

**ALLEGED SHIPMENT:** On or about April 19, 1945, by the Hormorgano Corporation, from Jamaica, N. Y.

**PRODUCT:** 5 12½-liter bottles of *estrogenic substance in oil* at Detroit, Mich.

**LABEL, IN PART:** "Estrogenic Substance in Corn Oil."

**NATURE OF CHARGE:** Misbranding, Section 502 (e), the label of the product failed to bear the common or usual name of each active ingredient since the label designation, "Estrogenic Substance," is not the specific name of any particular substance but is a generic name for a class of substances.

**DISPOSITION:** September 7, 1945. The Hormorgano Corporation, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

**1798. Misbranding of estrogenic substance. U. S. v. 10 Vials and 15 Vials of Estrogenic Substance. Default decrees of condemnation and destruction. (F. D. C. Nos. 16202, 16287. Sample Nos. 4237-H, 16540-H.)**

**LIBELS FILED:** May 23 and 29, 1945, Eastern District of Pennsylvania and Northern District of Illinois.

**ALLEGED SHIPMENT:** Between the approximate dates of January 23 and May 15, 1945, by the Metropolitan Laboratories, Inc., from New York, N. Y.

**PRODUCT:** 10 vials of *estrogenic substance* at Reading, Pa., and 15 vials of *estrogenic substance* at Chicago, Ill.

\*See also Nos. 1755, 1757, 1761, 1768, 1782, 1785, 1788, 1789, 1795.